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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,631	01/28/2004	Zhong Zhang	TPIP018X2	3752

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EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,631	ZHANG ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/13/2004*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *08/02/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Telephonic Discussion

A telephonic discussion of *August2, 2005* held to clarify the meaning of whether or not claim 7 was to be interpreted as being conjunctive in regard to items a) through n) or in the alternative with regard to items a) through n). The claim is to be interpreted as in the alternative and that "selected from the group consisting of" was missing from the claim. In response to this office action, it is incumbent upon applicant to properly amend the claim.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 13, 2004 has been considered.

Objection

The use trademarks in the specification has been noted and should be capitalized wherever they appear and be accompanied by the generic terminology. Preferably applicant should list the ingredients contained in the PROPOFLO™, RAPINOVET™ (on page 2 of specification lines 9+) at the time the invention was made. Note that over time the trademark can change and will not enable one skill in the art to carry out the same experiments.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being unpatentable by Glen et al., US 4,056,635.

Glen discloses an aqueous composition containing:

(a) a block copolymer (column 3 line 27) (claim 1),

(b) a polyethylene glycol (column 3 lines 29-30) (claim 1) and

(c) 2,6-diisopropylphenol (column 3 line 23-24) as in claim 1. Glen also discloses a formulation according to claim 1, where in the amount of 2,6-diisopropylphenol in claim 2 is:

at least 1% (w/v) of said formulation (column 3 line 22 see also line 62),

from 1to 5% (w/v) of said formulation (column 3 line 22 see also line 62),

from 1to 2% (w/v) of said formulation (column 3 line 22),

1% (w/v) of said formulation (column 3 line 65)

Glen also disclose administering propofol as an anaestetic to a patient that comprises of the formulation in claim 1 as disclosed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glen et al., US 4,056,635 ('635) and May et al., US 6,140,374 ('354) and Lee et al., US 6,743,436 B1 ('436).

Glen teaches an aqueous composition containing (claim 1 and 3), a block copolymer (column 3 line 27 to be P188 which is the same as Pluronic F68), a polyethylene glycol (column 3 lines 29-30), to be (PEG-200, 400, 600 as in claim 4) and 2,6-diisopropylphenol (column 3 line 23-24 as in claim 1). Glen also teach a formulation

(claim 2) according to claim 1, where in the amount of 2,6-diisopropylphenol is at least 15 (w/v) of said formulation (column 3 line 22 see also line 62), from 1to 5% (w/v) of said formulation (column 3 line 22 see also line 62), from 1 to 2% (w/v) of said formulation (column 3 line 22), 1% (w/v) of said formulation (column 3 line 65), a tonicity modifier to be dextrose (claim 5) at column 3 line 31, propylene glycol (column 3 line 29 as in claim 5), a formulation which further comprises citric acid (column 3 line 10 as in claim 6,). Glen also teach administering formulation as in claim 1 to a patient as an anesthetic, by administering an anesthetically effective amount of the propofol.

May teaches of a sterile pharmaceutical composition/formulation where in the amount of 2,6-diisopropylphenol in claim 2 is:

at least 1% (w/v) of said formulation (column 2 line 16), from 1to 5% (w/v) of said formulation (column 2 line 15), from 1to 2% (w/v) of said formulation (column 2 line 14), 1% (w/v) of said formulation (column 2 line 16). May also teaches the incorporation of benzyl alcohol (0.45%) at column 2 line 35-38, and disoduim EDTA as an antimicrobial agent.

Lee et al teach an aqueous solution comprising as in claim 7 (c) a poloxamer 188 in an amount of 8%, 4% PEG-400 and 1% of propofol at column 7 example 7.

The claims differ where Glen did not per se teach the combination in concentration of the block co-polymer to be 6 and 8% as claimed by applicant, nor of the polyethylene glycol concentration to be 2% nor the concentration of citric acid as in claim 8. However the patent teach a wide concentration range for co-polymer as 10-

20%, polyethylene glycol 5-20%, citric acid as 0.1% used to maintain the pH value of the formulation instead of an antimicrobial agent.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to formulate a sterile composition ranges replace the concentration as disclosed in the '635 patent with that of the applicant as the formulation contains all the necessary components for anesthesia in a patient. Although, Glen did not per se teach of the exact concentration of the components, Lee, however provided motivation to optimize the ranges of surfactants used with the lipid, based upon the examples given at column 6, where 4 grams of the surfactant and 0.5 g of PEG versus, 8 grams surfactant and 5 grams PEG, indicating concentration ranges can be optimized, based upon the lipid use as soluble lipid-soluble drugs are generally poorly soluble in water and possesses limitation as disclosed by Lee et al column 1 line 64+. Lee further explained at column 5 line 4+, the effect of selecting a suitable surfactant to increase the surface tension.

One of ordinary skill in the art would have been motivated to combine the teachings of Glen with that of May and Lee which result in the concentrations as claimed and obtained successful results in administering the formulation as an anesthetic to patients. One of the ordinary skill in the art would have known administering anesthesia to patients will vary as to tolerance, and the condition of the patient in need. It would have been obvious to one of ordinary skill in the art to add an antimicrobial to the solution to prevent microbial growth in compositions intended for

human and/or veterinary use. Therefore the skilled artisan would have incorporated an anti bacterial agent to the formulation.

One of ordinary skill in the art would have expected successful results and would have been motivated combining the teachings of Glen with that of May and Lee as the art recorgnizes the claimed formulation (claim 1) for use as an anesthesia.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
08/02/05

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